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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,669	08/16/2001	Masahiro Sakanaka	56238(71526)	4547

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EXAMINER	
KHARE, DEVESH	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,669	SAKANAKA ET AL.	
	Examiner	Art Unit	
	Devesh Khare	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-44,46,47,50 and 51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-44,46,47,50 and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's election filed on 5/17/2004 without traverse of claims 32-44,46-47 and 50-51 of Group I, is acknowledged.

Claims 1-31, 45 and 48-49 have been cancelled.

An action on the merits of claims 32-44,46-47 and 50-51 is contained herein below.

35 U.S.C. 112, first paragraph rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-44,46-47 and 50-51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention of record. The specification, while enabling a method of inducing apoptosis or apoptosis-like cell death of oligodendrocytes comprising administering an effective amount of a pharmaceutical composition comprising a therapeutic agent ginsenoside Rb_1, does not reasonably provide enablement for the treatment of diseases caused by injuries to nervous tissues or the spinal cord. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not

have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

The factors regarding undue experimentation have been summarized in *In re Wands,* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

(1) The quantity of experimentation necessary (time and expense);

(2) The amount of direction or guidance presented;

(3) The presence or absence of working examples of the invention;

(4) The nature of the invention;

(5) The state of the prior art;

(6) The predictability or unpredictability of the art;

(7) The breadth of the claims; and

(8) The relative skill of those in the art.

1. QUANTITY OF EXPERIMENTATION

With regard to factor one the quantity of experimentation needed, a method for the treatment of diseases caused by injuries to nervous tissues or the spinal cord comprising administering an effective amount of a pharmaceutical composition comprising a therapeutic agent ginsenoside Rb_1 would require undue experimentation. At the very least, experimentation correlative to establishing the broad spectrum of efficacy should be provided. The absence of specific disclosures or the correlation of data to support applicant's assertions, invites the skilled artisan to engage in undue experimentation, to treat the diseases caused by injuries to nervous tissues.

2. GUIDANCE PROVIDED

There is little guidance given in the specification as to the specific use of an effective amount of ginsenoside Rb_1 in a method for the treatment of diseases caused by injuries to nervous tissues or the spinal cord. This lack of guidance would indeed impose the burden of undue experimentation in determining the degree, if any, for the treatment of human health conditions set forth. There is not seen any guidance in the specification drawn to establishing a correlation between the use of an effective amount of the ginsenoside Rb_1 and the treatment of diseases caused by injuries to nervous tissues or the spinal cord. No guidance to use the ginsenoside Rb_1 for the treatment of diseases caused by injuries to nervous tissues or the spinal cord.

3. WORKING EXAMPLES IN SPECIFICATION

The EXAMPLES advanced in the instant specification are not seen as sufficient to support the breadth of the claims for the treatment of diseases caused by injuries to nervous tissues or the spinal cord. It is noted that Examples 1-9 provide intravenous infusion of ginsenoside Rb_1 and treatment of bedsore, corneal injury, chorea and dilated cardiomyopathy.

4. NATURE OF THE INVENTION

It is known in this art that certain compounds from ginseng root have efficacy in treating cerebral vascular disease. The exact mechanism of action and the effects of these compounds may be found in the U.S. Patent 4,708,949 (Liu).

5. STATE OF THE PRIOR ART

The instant claimed methods are drawn to a method for the treatment of diseases caused by injuries to nervous tissues or the spinal cord. The following references are cited to show the state of the prior art:

Liu, U.S. Patent 4,708,949.

Lim et al., Neuroscience Res. 28, 191-200, 1997.

6. THE PREDICTABILITY OF THE ART

To extrapolate the data from ginsenoside Rb_1, for the treatment of diseases caused by injuries to nervous tissues or the spinal cord is not seen to be disclosed in the prior art. Neither the specification nor the prior art provides adequate guidance for equivocating the treatment data for the ginsenoside Rb_1, the treatment of diseases caused by injuries to nervous tissues or the spinal cord. The asserted treatment of diseases caused by injuries to nervous tissues is not seen to be based upon data which would adequately substantiate the treatment of diseases caused by injuries to nervous tissues in a subject in need thereof.

7. BREATH OF THE CLAIMS

Claims 32-44,46-47 and 50-51 are drawn to a method for the treatment of diseases caused by injuries to nervous tissues or the spinal cord comprising administering an effective amount of a pharmaceutical composition comprising a therapeutic agent ginsenoside Rb_1.

8. THE RELATIVE SKILL IN THE ART

The relative skill in the art as it relates to a method for the treatment of diseases caused by injuries to nervous tissues or the spinal cord, is that of a Ph.D. or M.D. level. Presently, the instant specification is not seen to provide an enabling disclosure for the scope of the invention as set forth in claims, which encompass a method for the treatment of diseases caused by injuries to nervous tissues or the spinal cord comprising administering an effective amount of a pharmaceutical composition comprising a therapeutic agent ginsenoside Rb_1. It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves, see In re Gardner et al. 166 USPQ 138 (CCPA 1970). In the instant case, the amount of experimentation needed to verify the efficacy of ginsenoside Rb_1 for the treatment of diseases caused by injuries to nervous tissues or the spinal cord would indeed be voluminous and unduly burdensome in view of the teachings of the instant disclosure.

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 32-44,46-47 and 50-51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-12 of U.S. Patent No. 6,579,853 ('853).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the '853 patent discloses a method for therapy, prevention or treatment pf brain and nervous diseases, comprising administering to a subject in need of treatment ginsenoside Rb_1 or its salts. The '853 patent claims a method for therapy, prevention or treatment of brain and nervous diseases, comprising administering to a subject in need of treatment ginsenoside Rb_1 or its salts in a dose range of 1.67 mg/kg/day to 0.167 fg/kg/day wherein said method is encompassed by or has substantial overlap with the method of the instant claims. However, the instant method is for a method for the treatment of diseases caused by injuries to a patient to nervous tissues or to the spinal cord comprising the step of administering to a patient a therapeutically effective amount of a pharmaceutical composition comprising a therapeutic agent selected from ginsenoside Rb_1, its metabolites and salts thereof, wherein pharmaceutical contents besides the active agent ginsenoside Rb_1 are different from each other by which the method of the issued claims are accomplished.

The examiner notes the instant claims and the '853 patent claims do indeed substantially overlap and this obviousness-type double patenting rejection is necessary to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees.

Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Devesh Khare whose telephone number is (571) 272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at (571)272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,JD.
Art Unit 1623
October 4, 2004